Anthem Blue Cross and Blue Shield
2015 Staples Mill Road
Post Office Box 27401
Richmond, Virginia 23279

Anthem
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March 21, 2014

Virginia Department of Health
Attn: Robert O. Brennan, MD, Chairperson
ADAP Advisory Committee
P.O. Box 2448
Richmond, VA 23218-2448

RE: Formulary Addition Requests

Dear Dr. Brennan:

Thank you for your letter and the concern you have raised about the drugs included on our formulary for the treatment of HIV.

In the April 5, 2013 Letter to Issuers on Federally-facilitated and State Partnership Exchanges (the "Letter"), the Centers for Medicare and Medicaid Services (CMS) outlined in Appendix C of the Letter the certification standards issuers must meet when establishing prescription drug formularies for Qualified Health Plans. Among other criteria, CMS described the drug count service that it developed to compute the number of drugs per United States Pharmacopeia Convention (USP) category and class that must be offered by a formulary in a manner consistent with 45 C.F.R. 156.122 (a) (1). That regulation requires that a drug formulary that is compliant with essential health benefit (EHB) standards must cover the greater of (1) one prescription drug per USP category and class, or (2) the same number of prescription drugs in each USP category and class as the state EHB benchmark plan.

In the Letter, CMS explained that it computed the number of chemically distinct drugs covered by each EHB benchmark in each USP category and class by cross-walking National Drug Codes (NDCs) to categories and classes using the UPS Model Guidelines version 5.0. In doing so, different dosages of the same drug, different concentrations of the same active ingredient, brand and generic equivalents, and different delivery methods of the same drug were counted as one drug within a USP category and/or class.

Anthem's Pharmaceutical and Therapeutic Process utilized this standard to establish a compliant formulary for its plans in Virginia. In an effort to adhere to the guidelines, be clinically appropriate, and maintain plan designs that were attractive for a highly cost conscious group of individuals who have up to now not purchased health insurance because of cost, Anthem designed its formularies to generally meet but not exceed the CMS standards for the number of prescription drugs required in each USP category and class.

The Virginia benchmark formulary required the following counts for the antiviral HIV drug classes: HIV agents, non-nucleoside reverse transcriptase inhibitors (count of 5), HIV agents, nucleoside and non- nucleoside reverse transcriptase inhibitors (count of 11), HIV agents, other (count of 3) and HIV agents, protease inhibitors (count of 9). The Anthem formulary contains the above drug counts, and in addition the combination drug Atripla.

Despite the fact that other combination products were not included on our formulary, there is an exception process that has been established as required by 45 C.F.R. 156.122 under which access to a non-formulary drug might be granted. Based on Atripla's prevalence of use in comparison to other combination therapies, utilizing the exception process for the other combination products was the least disruptive to members moving to our products, and a clinically appropriate decision. Utilization of Atripla in our Virginia commercial market in 2013 represented 78% of the volume of combination therapies dispensed. In light of this we do not believe a change is warranted to our formulary at this time.

Anthem and its affiliates developed a single formulary which is used across all of our fourteen states for Exchange products in order to maintain consistency. There are a few deviations from this single formulary to meet state-specific requirements. With respect to the HIV drugs referenced in your letter, our formulary is the same across all of our states with the exception of Stribild which is covered in one state in order to meet that state's benchmark requirement. As such, Virginia's formulary construct for HIV drugs is being used across nearly all of Anthem's Exchange business.

We understand that Ryan White grant funds are made available in Virginia to provide premium assistance for Marketplace products only when their formularies that have more than one combination product. This approach would appear to not take into account those many patients already on an Atripla regimen that may prefer the Anthem product and network as the best one that meets their needs. We would urge changes to the grant criteria that would allow patients to make the best choice of product for them while still furthering the goal of the program.

Formulary determinations are subject to review from time to time. We are in the process of developing our formulary associated with our 2015 exchange products. In doing so we will take into account the information in your letter as well as other clinical resources that may be available. We appreciate the information you have provided very much.

Sincerely,

Jay Schukman, MD
RVP, Medical Director

JS:cab